

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Vemlidy (tenofovir alafenamide fumarate)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Vemlidy (tenofovir alafenamide fumarate)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Vemlidy (tenofovir alafenamide fumarate) may be approved when the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of chronic Hepatitis B infection;

OR

- III. Individual is using as prophylaxis for hepatitis B reactivation in the setting of immune suppression or in combination with hepatitis C direct-acting antiviral therapy (AASLD 2018);

OR

- IV. Individual a solid organ transplant recipient and using as prophylaxis for hepatitis B reactivation (AASLD 2018).

Requests for Vemlidy (tenofovir alafenamide fumarate) may not be approved for any of the following:

- I. Individual has end stage renal disease (estimated creatinine clearance below 15 mL/min) and is not receiving chronic hemodialysis; **OR**
- II. Individual has decompensated (Child-Pugh B or C) hepatic impairment.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Applicable	X	X	X	X	X	X	NA

Note: Vemlidy (tenofovir alafenamide fumarate) has black box warnings for severe exacerbations of hepatitis with drug discontinuation. Hepatic function should be monitored for several months after discontinuation of therapy to assess for severe exacerbation of hepatitis.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Terrault NA, Lok A, McMahon BJ, et al. Update on Prevention, Diagnosis, and Treatment of Chronic Hepatitis B: AASLD 2018 Hepatitis B Guidance. *Hepatology*. 2018; 67:1560-99.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 27, 2019.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2019. Updated periodically.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.

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